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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,073	12/31/2001	Joan M. Fallon	8016-1DIV	5373

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EXAMINER	
JIANG, DONG	
ART UNIT	PAPER NUMBER
1646	7

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/041,073	FALLON, JOAN M.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 25-45* is/are pending in the application.

4a) Of the above claim(s) *1-5,25-31 and 39-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-5 and 25-45* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED OFFICE ACTION

Applicant's election with traverse of Group III invention, claims 32-38, in Paper No. 6, filed on 16 June 2003 is acknowledged. The traversal is on the ground(s) that while the inventions I-III may be distinct, according to MPEP, if the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merit. This is not found persuasive because consistent with current patent practice, a serious burden may be established by (A) separate classification thereof; (B) a separate status in the art when they are classifiable together; or (C) a different field of search. In the instant case, besides the reasons set forth in the last Office Action, paper No. 5, Group III invention is patentably distinct from inventions I and II as shown by their separate classification, indicating each distinct subject has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. As stated in the MPEP 803, "a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP 802.02.". Further, a search is directed not only to art which would be anticipatory, but also to art that would render the invention obvious. Thus, the groups require divergent searches, and to search all groups of inventions would constitute serious burden.

The requirement is still deemed proper and is therefore made FINAL.

Currently, claims 1-5 and 25-45 are pending, and claims 32-38 are under consideration. Claims 1-5, 25-31 and 39-45 are withdrawn from further consideration as being drawn to a non-elected invention.

Formal Matters:

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are directed.

Claim 36 is objected to as it does not end in a period.

Objections and Rejections under 35 U.S.C. §101 and §112:

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 32 and the dependent claims 33-38 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 32, as written, does not sufficiently distinguish over biological markers as they exist naturally because the claim does not particularly point out any non-naturally occurring differences between the claimed product and the naturally occurring products. Naturally occurring stool comprises chymotrypsin. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "isolated" or "purified". See MPEP 2105.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 32 and the dependent claims 33-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claims 32-38 are directed to a biological marker in stool, such as stool chymotrypsin, for determining if an individual has, or can develop, a PDD, which reads on a biological marker in stool for the purpose of *diagnosing* PDD. However, such use of a biological marker in stool, chymotrypsin for example, is not supported by the present specification. The specification

merely discloses the use of chymotrypsin in a stool as an indicator for certain therapeutic regiment in patients *diagnosed* with a PDD, or for monitoring the efficacy of treatment of individuals *diagnosed* with a PDD. Nowhere in the specification had it indicated a use of stool chymotrypsin or any other biological markers that may be used for diagnosing a PDD, or "for determining if an individual has, or can develop, a PDD. The specification provides no guidance, nor working example as to how to use the stool chymotrypsin level for the diagnosis purpose as claimed. Further, in searching the prior art, the Examiner is not able to find any established art that applies a biological marker in stool for diagnosing a PDD. Therefore, it is totally unpredictable that a biological marker in stool such as stool chymotrypsin level is indicative of a PDD. As such, undue experimentation is required to determine such prior to using the present invention.

Due to the large quantity of experimentation necessary to determine whether a biological marker in stool such as stool chymotrypsin level is useful for diagnosing a PDD, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art, which has not established that a biological marker in stool is useful for determining a PDD, and the lack of predictability, undue experimentation would be required of the skilled artisan to use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 37 is indefinite because it is unclear what is meant by "marker comprises a quantitative level of the stool compound". The term "quantitative level" in the claim is a relative term which renders the claim indefinite. The term "quantitative level" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one

of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear how much is "quantitative level".

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 32 is rejected under 35 U.S.C. 102(b) as being anticipated by the well-known fact that biological markers exist in stools.

With respect to the limitation of the intended use for determining a PDD, it does not alter the nature of the biological marker. Therefore, such claim limitation adds no patentable weight to said composition.

Claims 32-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Dockter et al. (Padiatr. Padol., 1985, 20(3):257-65).

Dockter discloses a method for determining fecal chymotrypsin (FCT) in stool specimens of healthy and those with gastro-intestinal disease, and indicates that the FCT test may be preferred as diagnostic marker for differential diagnosis of exocrine pancreatic insufficiency. Thus, Dockter's FCT in stool anticipates claims 32, 33, 35-37 as being a biological marker in stool (as claim 32), and wherein the stool compound comprises chymotrypsin (as claim 33) as an indicator of pancreatic function (as claim 35), and is quantitative (as claim 37). With respect to the limitation of the intended use for determining a PDD, such as autism in claims 32 and 36, it does not alter the nature of the biological marker. Therefore, such claim limitation adds no patentable weight to said composition. With respect to claim 34, as chymotrypsin is a proteolytic enzyme secreted by pancreas for protein digestion, it inherently reflects pancreatic function. Therefore, the reference also anticipates claim 34. With respect to claim 38, as Dockter' FCT .test is for differential diagnosis of exocrine *pancreatic insufficiency* in patients with gastro-intestinal *disease*, FCT is indicative of the need

for biological treatment, such as supplemental therapy of the enzyme. As such, the reference anticipates claim 38.

Conclusion: No claim is allowed.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

- Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

Dong Jiang, Ph.D.
Patent Examiner
AU1646
8/18/03